EXHIBIT A

NAILAH K. BYRD
CUYAHOGA COUNTY CLERK OF COURTS
1200 Ontario Street
Cleveland, Ohio 44113

Court of Common Pleas

New Case Electronically Filed: COMPLAINT
August 26, 2021 10:28

By: DENNIS R. LANSDOWNE 0026036

Confirmation Nbr. 2336305

BRIAN CHERKALA, ET AL.

CV 21 952213

vs.

Judge: WILLIAM F. B. VODREY

LIVANOVA DEUTSCHLAND GMBH, ET AL.

Pages Filed: 45

IN THE COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO

BRIAN CHERKALA
c/o Spangenberg Shibley & Liber
1001 Lakeside Avenue East
Suite 1700
Cleveland, Ohio 44114

and

YVONNE CHERKALA
c/o Spangenberg Shibley & Liber
1001 Lakeside Avenue East
Suite 1700
Cleveland, Ohio 44114

Plaintiffs

vs.

LIVANOVA DEUTSCHLAND GMBH (f/k/a SORIN GROUP DEUTSCHLAND GMBH)
Lindberghstrasse 25 Muenchen, 80939
Germany

and

LIVANOVA USA, INC.
c/o Universal Registered Agents, Inc.,
Statutory Agent
3958-D BROWN PARK DRIVE
HILLIARD OH 43026

and

LIVANOVA HOLDING USA, INC.
c/o Universal Registered Agents, Inc.,
Statutory Agent
3958-D BROWN PARK DRIVE
HILLIARD OH 43026

and

CASE NO.

JUDGE

[Related Case No. CV 20 936048]

COMPLAINT

[***Jury Demand Endorsed Hereon***]

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CLEVELAND CLINIC FOUNDATION)
c/o CT Corporation Systems, Statutory)
Agent)
4400 Easton Way)
Suite 125)
Columbus, Ohio 43219)
)
)

Defendants

INTRODUCTION

1. On August 28, 2017, Plaintiff Brian Cherkala underwent open-heart surgery to replace a heart valve. During surgery, Plaintiff's doctor utilized a contaminated and defective Stockert 3T Heater-Cooler System ("3T"), which introduced a non-tuberculosis mycobacterium into Plaintiff's chest cavity and contaminated the newly installed heart valve. Over the next year, the mycobacterium spread throughout Plaintiff's body causing a chronic, systemic infection affecting multiple organ systems, culminating in a second open-heart surgery to replace the contaminated heart valve. Plaintiff has suffered and continues to suffer significant general and special damages as a result of the Defendants' negligence, defective manufacture of their product, and callous failure to warn of the product's known dangers.

PARTIES AND JURISDICTION

2. At all times relevant, Plaintiff Brian Cherkala was and is a resident of the State of Ohio.

3. At all times relevant, Plaintiff Yvonne Cherkala was and is a resident of the State of Ohio.

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4. Defendant LivaNova Deutschland GmbH (f/k/a Sorin Deutschland GmbH) ("Sorin") is a foreign for-profit corporation headquartered in Munich, Germany. Sorin designed, manufactured and marketed the Stockert 3T Heater-Cooler System.

5. Defendant LivaNova Holding USA, Inc. (f/k/a Sorin Group USA, Inc.) ("Sorin USA") is a U.S. designer, manufacturer, marketer and distributor of the Stockert 3T Heater-Cooler System with a principal place of business in Arvada, Colorado.

6. On information and belief, Defendant LivaNova USA, Inc. (f/k/a Cyberonics, Inc.) is a U.S. designer, manufacturer, marketer and distributor of the Stockert 3T Heater-Cooler System with a principal place of business in Houston, Texas.

7. Defendants LivaNova Deutschland GmbH, LivaNova Holding USA, Inc., and LivaNova USA, Inc. are referred to collectively as the "manufacturer Defendants."

8. Personal jurisdiction exists over manufacturer Defendants in the United States and in Ohio due to the general and specific contacts they maintain. Defendants maintain those contacts presently and did so at all times material to this action.

9. Defendant Cleveland Clinic Foundation ("Cleveland Clinic") is a healthcare corporation located in Cuyahoga County.

10. Venue is proper in Cuyahoga County pursuant to Ohio Rules of Civil Procedure 3(C)(2), and Plaintiff seeks damages in excess of the Court's minimum jurisdiction.

FACTS

11. June 1, 2016, the United States Food and Drug Administration issued a Safety Communication to healthcare providers with information about non-tuberculosis

infections associated with the use of Stockert 3T Heater-Cooler Systems in U.S. patients who had undergone cardiothoracic surgeries.

12. The bacterium at issue, *M. Chimera*, is a subspecies of non-tuberculosis mycobacterium ("NTM") that occurs naturally in the environment and rarely causes illness. However, *M. Chimera* poses a unique risk to patients whose organs and chest cavities are directly exposed to the bacteria during surgery.

13. *M. Chimera* generally takes anywhere from several weeks to six years before manifestation of an infection, which commonly results in cardiovascular or respiratory illness, or a disseminated infection spread throughout the body.

14. Symptoms of *M. Chimera* infection, including other NTM subspecies such as *M. Abscessus*, may include any of the following: persistent fever, pain, night sweats, joint and muscle pain, unexplained weight loss and fatigue.

15. The diagnosis of an NTM infection requires targeted culturing and/or molecular diagnostic testing, the results of which take at least 6-8 weeks.

A. Defendants' 3T Heater-Cooler Systems as the Infection Source

16. The Cleveland Clinic utilized Stockert 3T Heater-Cooler Systems in its cardiothoracic surgeries, including Plaintiff's surgery, which were designed, manufactured, marketed and/or sold by Defendants.

17. The 3T System regulates blood temperature by circulating water through tubes into a heat exchanger where blood is pumped into separate chambers during surgery. The water tanks and other areas through which water passes aerosolize a vapor containing NTM which exits out of the device and is pushed into the ambient air of the operating room through the System's exhaust fan. If placed in the operating room,

contaminated vapor from the 3T System directly enters the sterile surgical field and the patient's open body.

18. Published studies dating back to the 1980s confirm that NTM is commonly found in water and has a high propensity to become airborne (aerosolize) through natural processes.[1]

19. The potential for contaminated water from heater-cooler devices to infect patients intraoperatively was recognized by the medical and scientific community as early as November 2002.[2]

20. Invasive cardiovascular infections identified as NTM have been reported in Switzerland, Germany and the Netherlands since 2011.[3]

21. A public health investigation in Switzerland following six patient infections since 2011 included microbiological examinations of environmental samples that identified *M. Chimaera* contamination in heater-cooler units, including water samples from inside the units. Samples of the ambient air were positive for *M. Chimaera* when the units were running, but negative when they were turned off.[4]

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[1] *See e.g.*, Wendt, *et al.*, Epidemiology of Infection by Nontuberculous Mycobacteria, III. Isolation of Potentially Pathogenic Mycobacteria from Aerosols, American Review of Respiratory Disease, 1980 ("Field experiments have confirmed the existence of a natural mechanism for the transfer of significant numbers of mycobacteria from water to air."); Falkinham, Mycobacterial Aerosols and Respiratory Disease, Emerging Infectious Diseases, July 2003 ("Environmental opportunistic Mycobacteria are present in drinking water, resistant to disinfection, able to provoke inflammatory reactions, and readily aerosolized.").

[2] *See* The Heater-Cooler Unit—A Conceivable Source of Infection, Weitkemper, *et al.*, The Journal of the American Society of Extra-Corporeal Technology, 2002.

[3] ECDC Rapid Risk Assessment, Invasive Cardiovascular Infection by Mycobacterium Chimaera Potentially Associated with Heater-Cooler Units Used During Cardiac Surgery, April 30, 2015, available online at https://www.ecdc.europa.eu/en/publications-data/invasive-cardiovascular-infection-mycobacterium-chimaera-potentially-associated (last accessed on August 13, 2020).

[4] Subsequent studies have further confirmed that the 3T aerosolizes *M. Chimaera* when powered on. *See e.g.*, Lyman, *et al.* Invasive Nontuberculous Mycobacterial Infections among Cardiothoracic Surgical Patients Exposed to Heater-Cooler Devices, Emerging Infectious Diseases, May 2017; Gotting, *et al.*,

22. In April 2011, the FDA visited Defendant, Sorin, in Munich, Germany for a plant inspection and to discuss safety concerns with the 3T approved in 2005 through the 510(k) process. The FDA advised the company that its 3Ts harbored dangerous bacteria and that it had failed to make a proper risk assessment for cleaning the devices to prevent bacterial infections in patients exposed in the operating room.

23. Defendants conceded to the FDA that this particular patient risk was "not considered" because it was "not of concern."

24. During this inspection, the FDA also advised the company that the bacterial growth charts it used to justify the original instruction for device disinfection every 14 days allowed bacterial overgrowth well in excess of safe standards in *just one and a half days*. The company admitted to the FDA that its cleaning instructions did not meet these standards and that it had no information to support the cleaning methods it disseminated to U.S. purchasers.

25. More than four years later, on July 15, 2015, Defendants issued a Class 2 Recall of the 3T's instructions for use ("IFU") because of "[p]otential colonization of organisms, including Mycobacteria, in Sorin Heater Cooler Devices, if proper disinfection and maintenance is not performed per instructions for use."

26. The recall directed customers to follow the new cleaning and disinfection procedures outlined in a Field Safety Notice issued by Defendants on June 15, 2015.

Heater-Cooler Units: Contamination of Crucial Devices in Cardiothoracic Surgery, Journal of Hospital Infection, February 2016; Sommerstein, *et al.*, Transmission of *Mycobacterium Chimaera* from Heater-Cooler Units during Cardiac Surgery Despite an Ultraclean Air Ventilation System, Emerging Infectious Diseases, June 2016.

27. According to this Field Safety Notice, the company's hygiene concept was "enhanced"[5] by introducing the following modifications:

a. Use filtered tap water when filling the device;

b. To make disinfection easier, switch from three different cleaning procedures (every five days, every two weeks and every three months), to just two (every seven days and every fourteen days);

c. The option to use peracetic acid instead of Clorox for disinfection;

d. Use hydrogen peroxide in low dose for device preservation;

e. Include all external tubing, bottles and buckets in the disinfection process;

f. Change to polyethylene tubing that meets national drinking water standards; and

g. Unused heater-coolers should be disinfected bi-weekly.

28. Upon information and belief, Defendants knew or should have known that design and/or manufacturing defects in the 3T renders it prone to bacterial colonization and transmission, *regardless of the cleaning and disinfection procedures used*.[6]

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[5] A month prior to the recall, in May 2015, Defendants informed customers that devices that had not been maintained according to the manufacturers' IFUs required a mechanical deep disinfection process to remove bacterial colonization, referred to as "biofilm".

[6] *See e.g.*, Garvey, *et al.*, Decontamination of Heater-cooler Units Associated with Contamination by Atypical Mycobacteria, Journal of Hosp. Infection, March 2016 (finding that Defendants' decontamination protocol was inadequate and that removal of internal tubing was required to achieve water quality in 3Ts); Marra, *et al.*, Mycobacterium Chimaera Infections Associated with Contaminated Heater-Cooler Devices for Cardiac Surgery: Outbreak Management, Clinical Infectious Diseases, April 19, 2017 ("Despite adherence to these [manufacturer] recommendations for use of sterile or filtered water, and regular water circuit disinfection and tubing changes, *M. Chimaera* contamination will persist...investigators using far more intensive attempts at disinfection have been unable to eradicate *M. Chimaera* from 3T HCDs.")(internal citations omitted).

29. Manufacturing and User Facility Device Experience ("MAUDE") reports, such as one reported to the FDA on July 7, 2016, evidence that even mechanical deep disinfection followed by the use of filtered water, new water hoses, and three cycles of Defendants' new cleaning procedure fail to eliminate high bacteria counts in the 3T.[7]

B. Additional NTM Outbreaks and Regulatory Agency Responses

30. The risk of NTM transmission with the 3T is not unique to the Cleveland Clinic. In November 2015, Penn State Milton. S. Hershey Medical Center in Hershey, PA announced that 2300 patients had been exposed to NTM via its 3Ts and later confirmed multiple infections and deaths linked to the devices. On September 20, 2016, yet another Pennsylvania hospital, Penn Presbyterian Medical Center in Philadelphia, announced patient infections linked to the 3T.

31. Hospitals throughout the U.S. states have reported patient infections and/or device contamination with NTM. For example, the University of Iowa Hospitals and Clinics has confirmed multiple *M. Chimaera* infections, including deaths, attributed to the 3T. In May 2016, Swedish Medical Center in Seattle, Washington issued letters notifying certain cardiac bypass patients that it had tested and found NTM in several of its 3Ts.

32. Many hospitals have either discontinued using the 3T or have moved the 3T into a separate room to prevent contaminated aerosols from reaching the surgical field.

33. On October 21, 2015, the U.S. Centers for Disease Control and Prevention ("CDC") issued an Interim Practical Guidance communication to raise awareness among

[7] *See also*, ECDC Rapid Risk Assessment, *supra* ("In Switzerland, cleaning and decontamination of the heater-cooler units was followed by recontamination. A new heater-cooler unit that initially tested negative for *M. Chimaera* at the hospital tested positive three months after purchase and installation.")

health departments, healthcare facilities and providers of the association between NTM infections and the use of heater-cooler devices.

34. On December 29, 2015, the FDA sent Defendants a warning letter advising that 3Ts were subject to refusal of admission into the U.S. until they resolved several FDA violations, including the FDA's determination that the 3Ts were adulterated[8] and misbranded and lacked requisite safety validation for several design changes to both the device itself as well as a series of revised disinfection instructions. The FDA's findings were based on its inspections of the company's Munich, Germany and Arvada, Colorado production facilities.

35. In the letter, the FDA identified various design change orders dating back to December 11, 2012 which had never been documented, validated and/or submitted to the FDA for approval.

36. The letter also identified several changes to the disinfection instructions, dating back to December 20, 2011, which had never been reported to the FDA and which, like the current disinfection instructions, lacked proper efficacy validation.

37. In April 2016, a Euro Surveillance study following environmental investigations conducted between July 2014 and June 2015 determined that certain 3Ts manufactured at Defendants' Munich, Germany production facility were contaminated with NTM on the production line or elsewhere at Defendants' manufacturing facility.

38. A June 1, 2016 FDA Safety Communication following the Euro Surveillance findings noted that "this paper suggests a direct link between the *M.*

[8] Under the Federal Food, Drug and Cosmetic Act, a medical device is "adulterated" if the methods used in, or the facilities or controls used for their manufacture, packing, storage or installation are not in conformity with current good manufacturing practice requirements of the Quality System regulation.

Chimaera to which European patients were exposed and became infected during open-chest cardiac surgery, and one specific heater-cooler model—the 3T." The FDA cautioned U.S. purchasers of the 3T that if they purchased their units before September 2014, they may have been shipped from Defendants' factory contaminated with *M. Chimaera*.[9]

39. In June 2016, a study published in the Journal of Emerging Infectious Diseases confirmed the airborne transmission of NTM via 3Ts due to the ability of the System's exhaust fan to disrupt the ultraclean air ventilation systems of operating rooms. According to the study, aerosolization from the 3T carried NTM a distance of up to 5 meters from the device.

40. On June 2-3, 2016, the FDA hosted a Circulatory System Devices Panel for the Medical Devices Advisory Committee to address the public health risk posed by heater-cooler devices, and in particular, the 3T.

41. During this Panel, the FDA noted that nearly 90% of the Medical Device Reports ("MDR") it received between January 2010 and February 2016 citing device contamination and patient infection were attributed to the 3T.

42. During this Panel, Defendants' representatives admitted that the company was in the process of retrofitting existing 3Ts with new design features, including, but not limited to, changing tubing materials from PVC to polyethylene to limit biofilm formation and the introduction of plugs in the water circuit to prevent sitting water.[10]

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[9] June 1, 2016 FDA Safety Communication, available at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm504213.htm (last accessed on January 24, 2017).

[10] [11] Defendants' website advised overseas customers (but not U.S. customers) that it had released a "vacuum and sealing upgrade and aerosol collection kit" whereby a disposable canister is attached to the

43. On October 13, 2016, the CDC released the results of genome sequencing studies confirming that patient infections in Pennsylvania and Iowa were directly linked to Defendants' Munich, Germany manufacturing site.[11]

44. That same day, the FDA issued an updated Safety Communication, instructing hospitals throughout the country to discontinue using 3Ts manufactured before September 2014 due to evidence of "point source contamination at the production site".[12]

45. A later study titled "Global Outbreak of Severe Mycobacterium Chimaera Disease After Cardiac Surgery: A Molecular Epidemiological Study" also concluded that 3Ts were most likely contaminated with *M. Chimaera* during manufacturing.[13]

46. Subsequent studies published in 2017 further confirm "an ongoing international outbreak of *M. Chimaera* infection following cardiac surgery" and that "all *M. Chimaera* infections have been attributed to a specific make/model of HCU (Sorin 3T, LivaNova PLC, formerly Sorin Group Deutschland GmbH).[14]

3T and connected to a vacuum system to capture and divert NTM aerosols from the surgical field. *See* http://www.livanova.sorin.com/products/cardiac-surgery/perfusion/hlm/3t-out-us (last accessed on July 12, 2017).

[11] *See* CDC Morbidity and Mortality Weekly Report for October 14, 2016, available online at https://www.cdc.gov/mmwr/volumes/65/wr/mm6540a6.htm?s_cid=mm6540a6_w (last accessed on June 20, 2017). Multiple studies have since linked the same strain of *M. Chimaera* to patient infections following use of the 3T in geographically sequestered locations such as Australia, Canada, France, Germany, Hong Kong, Ireland, the Netherlands, Spain and Switzerland. *See e.g.,* Svensson, *et al.*, *Mycobacterium chimaera* in heater–cooler units in Denmark related to isolates from the United States and United Kingdom, Emerg Infect Dis., March 2017, available online at https://wwwnc.cdc.gov/eid/article/23/3/16-1941_article (last accessed on June 20, 2017); *see also* Walker, *et al.,* Microbiological Problems and Biofilms Associated with Mycobacterium Chimaera in Heater-cooler Units Used for Cardiopulmonary Bypass, Journal of Hospital Infection, April 26, 2017 (collecting data of global *M. Chimaera* infections)

[12] *See* October 13, 2016 "UPDATE: Mycobacterium Chimaera Infections Associated with LivaNova PLC (formerly Sorin Group Deutschland GmbH) Stockert 3T Heater-Cooler System: FDA Safety Communication", available online at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm520191.htm (last accessed on June 20, 2017)

[13] Published online July 12, 2017 in the Lancet Infectious Diseases journal.

[14] *See e.g.,* Walker, *et al., supra*.

FACUTAL ALLEGATIONS SPECIFIC TO PLAINTIFF BRIAN CHERKALA

47. On August 28, 2017, Plaintiff underwent open-heart surgery to replace his heart valve at the Cleveland Clinic Main Campus.

48. To perform Plaintiff's open-heart surgery, his physicians utilized one of Defendants' Stockert 3T Heater-Coolers.

49. The 3T Heater-Cooler used during Plaintiff's surgery was defective and contaminated with NTM.

50. In August of 2018, Plaintiff became chronically ill, suffering from persistent fevers, night sweats, and a chronic cough.

51. Plaintiff's physicians were unable to immediately diagnose his illness, and treatment was proving ineffective.

52. On December 6, 2018, Plaintiff's physician discovered Plaintiff was infected with NTM, specifically *Mycobacterium chimera,* which was introduced into Plaintiff's body during his surgery via the defective and contaminated 3T System.

53. Plaintiff's *Mycobacterium chimera* infection spread throughout his body, inflaming his spleen, liver, and other organs.

54. To fight this infection, Plaintiff was required to take extended doses of strong antibiotics and steroids, which carried painful and debilitating side effects.

55. The *Mycobacterium chimera* infection also compromised Plaintiff's artificial heart valve, which required replacement via a second open-heart surgery.

56. Plaintiff is still battling the *Mycobacterium chimera* infection and continues to suffer the harsh effects of both the bacterial infection and the treatment of it.

57. Since his surgery, Plaintiff has continuously treated with Defendant Cleveland Clinic Foundation, and never terminated his physician-patient relationship with the Cleveland Clinic Foundation.

FIRST CLAIM FOR RELIEF

PRODUCT DEFECT IN MANUFACTURE OR CONSTRUCTION

(by Plaintiff Brian Cherkala against all Manufacturer Defendants)

58. Plaintiffs hereby incorporate by reference each and every allegation set forth in the preceding paragraphs.

59. Defendants qualify as a "manufacturer" as that term is defined in R.C. §2307.71(a).

60. This claim is being brought pursuant to R.C. §2307.74.

61. The Stockert 3T Heater-Cooler used in Plaintiff's open-heart surgery was defective in its manufacture and construction when it left the hands of the manufacturer(s) in that it deviated from product specifications and performance standards, thereby posing a serious risk of injury and death.

62. As a direct and proximate result of Plaintiff's exposure to Defendants' defective product, Plaintiff endured serious physical and mental injury, was forced to seek medical attention and incur medical expenses and suffered additional general and special damages to be proven at trial.

SECOND CLAIM FOR RELIEF

PRODUCT DEFECT IN DESIGN OR FORMULATION

(by Plaintiff Brian Cherkala against all Manufacturer Defendants)

63. Plaintiffs hereby incorporate by reference each and every allegation set forth in the preceding paragraphs.

64. This claim is being brought pursuant to R.C. §2307.75.

65. The Stockert 3T Heater-Cooler used in Plaintiff's open-heart surgery was defective in its design in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design, or it was more dangerous than the ordinary consumer would expect.

66. As a direct and proximate result of Plaintiff's exposure to Defendants' defective product, Plaintiff endured serious physical and mental injury, was forced to seek medical attention and incur medical expenses and suffered additional general and special damages to be proven at trial.

THIRD CLAIM FOR RELIEF

PRODUCT DEFECT DUE TO INADEQUATE WARNING AND/OR INSTRUCTION

(by Plaintiff Brian Cherkala against all Manufacturer Defendants)

67. Plaintiffs hereby incorporate by reference each and every allegation set forth in the preceding paragraphs.

68. This claim is being brought pursuant to R.C. §2307.76.

69. The Stockert 3T Heater-Cooler used in Plaintiff's open-heart surgery was defective due to inadequate warning or instruction because Defendant knew or should have known that the product created significant risks of serious bodily harm to consumers

and Defendant failed to adequately warn or instruct of such risks as a manufacture exercising reasonable care would have done.

70. As a direct and proximate result of Plaintiff's exposure to Defendants' defective product, Plaintiff endured serious physical and mental injury, was forced to seek medical attention and incur medical expenses and suffered additional general and special damages to be proven at trial.

FOURTH CLAIM FOR RELIEF

PRODUCT DEFECT IN FAILURE TO CONFORM TO REPRESENTATIONS

(by Plaintiff Brian Cherkala against all Manufacturer Defendants)

71. Plaintiffs hereby incorporate by reference each and every allegation set forth in the preceding paragraphs.

72. This claim is being brought pursuant to R.C. §2307.77.

73. Defendants' product was defective in that, when it left the control of Defendants, the product did not conform to representations made by Defendants.

74. As a direct and proximate result of Plaintiff's exposure to Defendants' defective product, Plaintiff endured serious physical and mental injury, was forced to seek medical attention and incur medical expenses and suffered additional general and special damages to be proven at trial.

FIFTH CLAIM FOR RELIEF

NEGLIGENCE

(by Plaintiff Brian Cherkala against all Manufacturer Defendants)

75. Plaintiffs hereby incorporate by reference each and every allegation set forth in the preceding paragraphs.

76. Defendants had a duty to exercise reasonable care in the manufacture, sale and distribution of their product, the Stockert 3T Heater-Cooler, into the stream of commerce, including a duty to assure that their product did not pose a significantly increased risk of bodily harm.

77. Defendants failed in their duty to exercise ordinary care in the sale, quality assurance, quality control, labeling, instructions, marketing, distribution of their product into interstate commerce, and post-marketing warnings and instructions in that Defendants knew or should have known that individuals such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care.

78. As a direct and proximate result of Defendants' negligence, Plaintiff endured serious physical and mental injury, was forced to seek medical attention and incur medical expenses and suffered additional general and special damages to be proven at trial. All the foregoing injuries and damages are permanent.

SIXTH CLAIM FOR RELIEF

NEGLIGENCE

(By Plaintiff Brian Cherkala against Defendant Cleveland Clinic Foundation)

79. Plaintiffs hereby incorporate by reference each and every allegation set forth in the preceding paragraphs.

80. The Stockert 3T Heater-Cooler Systems purchased by Cleveland Clinic purchased from the manufacturer defendants, including the unit utilized during plaintiff's surgery on August 28, 2017 required scheduled cleaning and disinfection of each unit, including its various components, as specified by the manufacturers' written Operating Instructions.

81. On information and belief, nonmedical technicians and/or engineers performed all maintenance, repair, disinfection, and cleaning of Stockert 3T Heater-Cooler units owned and/or used by the Cleveland Clinic.

82. Prior to plaintiff's cardiac surgery defendant Cleveland Clinic failed to properly maintain, clean and disinfect the Stockert 3T Heater-Cooler Systems at appropriate intervals as recommended by the manufacturers, thereby permitting the unit to become colonized with M. Chimera which was, in turn, introduced into plaintiff's bloodstream.

83. Furthermore, the Cleveland Clinic negligently failed to train and supervise the nonmedical technicians and/or engineers responsible for performing all maintenance, repair, disinfection, and cleaning of the Stockert 3T Heater-Cooler units owned and/or used by the Cleveland Clinic.

84. Subsequent to the Class 2 Recall issued by the manufacturer defendants on June 15, 2015, a 3T Loaner Program was instituted, whereby Cleveland Clinic was provided with the opportunity to replace its defective Sorin 3T Heater-Cooler units with new uncontaminated heater-cooler devices.

85. Contrary to the best interests and safety of its cardiac surgery patients, including plaintiff, Cleveland Clinic declined replacing its defective heater-cooler units and further failed to implement recommended corrective cleaning/disinfection actions in order to prevent M. Chimera infections of its cardiac surgery patients.

86. As a direct and proximate result of the negligence of Cleveland Clinic, combining with the wrongful conduct of the manufacturing defendants, plaintiff endured serious physical and mental injury, was forced to seek medical attention, and incur

medical expenses and suffered additional general and special damages to be proven at trial. All of the foregoing injuries and damages are permanent.

SEVENTH CLAIM FOR RELIEF

LOSS OF CONSORTIUM

(by Plaintiff Yvonne Cherkala against all Defendants)

87. Plaintiffs hereby incorporate by reference each and every allegation set forth in the preceding paragraphs.

88. As a result of Defendants' negligence, Plaintiff Yvonne Cherkala, the wife of Brian Cherkala, has suffered loss of services and consortium, has been forced to incur medical and other expenses and lost wages. All of these injuries are permanent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Brian and Yvonne Cherkala pray for judgment against the Defendants, jointly and severally, for compensatory damages in an excess of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), together with attorneys' fees and costs and any other relief this Court deems just and appropriate.

TRIAL BY JURY REQUESTED

Respectfully submitted,

/s/ Dennis R. Lansdowne
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Electronically Filed 08/26/2021 10:28 / / CV 21 952213 / Confirmation Nbr. 2336305 / CLAJB